REASONS FOR ALLOWANCE

Reasons for Allowance of amended Claim 19 in light of Bredesen or other prior art:

Claim 19 recites a stethoscope whose functions can be expanded by transferring software via a digital communications means to be stored and executed in the stethoscope. The closest prior art, Bredesen (US 5,010,889) individually or in combination with other prior art (a) does not recite features recited in the claimed invention and (b) there is no suggestion or motivation for the claimed invention in the prior art references taken individually or in combination.

Considering the specific elements of amended Claim 19 that differ from the Bredesen patent, the claim recites:

> **Nonvolatile digital memory means selected from a group consisting of Flash memory, EEPROM, and magnetic media,**

Bredesen discloses 2 types of memory – (i) volatile random access memory (RAM) which **loses its data** when the rechargeable batteries discharge and (ii) non-volatile memory that **cannot be written to with new software**, as claimed in the present invention. The memory claimed in the present invention is **both rewriteable and non-volatile** and therefore provides for the transfer and **storage** of software. This is not possible using Bredesen's memory and is not suggested or motivated in the prior art individually or in combination.

> **One or more software programs, executable by said central processing unit, which expand the functions executed by said stethoscope,**
>
> **Said functions comprising medical measurement, information processing and communications functions,**

The present invention recites a means for expanding stethoscope functions by means of transferring software. Bredesen makes no suggestion that (i) **software** can be **transferred** to his stethoscope invention or (ii) that there is any suggestion or motivation to **expand the functions** of the stethoscope by any means whatsoever. There is also no suggestion motivated by any other prior art to expand functions via software transfer.

> **Wherein said software programs are transferred via said digital communications means, stored in said nonvolatile digital memory means, and executed by said central processing unit.**

Bredesen and other prior art, individually or in combination, does not (i) disclose the transfer of software programs via a digital communications means (ii) disclose memory that has the properties to, or connected such that it can, provide for the non-volatile storage of software, or (iii) suggest the expansion of functions of a stethoscope as claimed in the present invention.

The difference between Bredesen and the present invention as claimed is substantial. Whereas the present invention recites software transfer, Bredesen discloses heart sounds waveform transfer. Whereas the present invention recites non-volatile memory to store transferred software, Bredesen discloses only volatile memory for heart sound memory and

volatile memory is entirely unsuited to software storage in a portable device such as a stethoscope. Whereas the present invention recites expansion of functions, Bredesen individually or combined with other prior art makes no suggestion or motivation for expanding the functions of a stethoscope. There are simply too many inventive steps required between Bredesen and the present invention.

Given that there is no suggestion or motivation for the transfer of software or the expansion of functions for a stethoscope, it is therefore clear that the only way to invent the present invention from the prior art is through a hindsight reconstruction of Applicant's claims.

(Applicant has previously communicated with Examiner via meeting, telephone and fax highlighting further differences between Bredesen and the present invention with regards to software, memory, data port design and hardware design, demonstrated with physical embodiments of the present invention. This information is not repeated here, but provides further argument in support of allowance.)

Reasons for Allowance of Claim 19 in light of KSR v. Teleflex.

In light of KSR Int'l Co. v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), the Court has argued for consideration of "common sense" and other considerations beyond a literal reading of the prior art in order to determine obviousness. The question is therefore whether the present invention is obvious given both knowledge and common sense on the part of those skilled in the art, even if the prior art does not teach, suggest, or motivate the claimed invention.

The claimed invention concerns the **expansion of the functions of a stethoscope via the transfer of software via a data communications means**, said software being stored in a non-volatile memory. In KSR, the Court stated that "Often it will be necessary ... to look to the effects of demands known to the design community or present in the marketplace and to the background knowledge possessed by a person having ordinary skill." It is therefore pertinent to consider whether one with ordinary skill, using common sense, might modify Bredesen and other prior art to invent a stethoscope with expanded functions achieved by downloading software.

Considering first the "marketplace" and "demands known to the design community" aspect of KSR, consider that the priority date for the present invention is October 5th 1998. There have therefore been nine years of marketplace activity following the priority date. In this time, virtually every stethoscope manufacturer has released multiple generations of electronic stethoscopes. To date, to Applicant's knowledge as a participant in this marketplace, Applicant is the only inventor to have released a stethoscope with software transfer and storage capability as claimed in the present invention. The closest prior art, the Bredesen patent, was issued in April 1991, and the Bredesen invention was marketed from about 1994 until about 2000. The Bredesen device, essentially the Bredesen invention reduced to practice, did not possess software transfer capability. Other inventors have had 16 years to apply "common sense" to his invention and device, and produce an expandable stethoscope with software transfer capability, yet we so no such product in the marketplace.

The Bredesen patent, and subsequent reduction to practice in the marketplace, comprises a device that facilitates the transfer of heart sounds i.e. medical measurements from the stethoscope to a plotter or an external storage device for archiving. It is commonplace to plot medical waveforms, it is commonplace to save medical records for archiving. Yet this is procedurally and conceptually entirely different from expanding the functions of a stethoscope through the downloading of new software. One skilled in the art, using common sense, would not be expected to make the leap from plotting a waveform to inventing a software-upgradeable medical device. There are simply too many inventive steps, and the invention can only be reconstructed from the prior art using hindsight. Given that those skilled in the art have not demonstrated such hindsight in the marketplace is further evidence that the inventive steps are too substantial to be obvious.

In another aspect of KSR, the Court's argues that that the "background knowledge possessed by a person having ordinary skill" should be considered. Medical devices, including stethoscopes, are regulated in the United States by the US Food and Drug Administration (FDA). A device is approved by the FDA with a given, fixed, software configuration. Modifying the software constitutes a design change that may require further FDA approval. The testing procedures for any given software version are arduous and specific to that version of software. Applying "common sense", those practicing the art work towards one approved, thoroughly tested version of software for a medical device, and are loathe to make further changes. The concept of facilitating software changes through a communications means on the device, thereby changing its features easily flies in the face of "common sense" to those practicing the art of medical device invention. It is entirely non-obvious that a medical device, and a stethoscope in particular, can ort should be provided with this level of software flexibility with an expectation of a successful result.

Another feature claimed in the present invention that as yet does not exist in the marketplace is the feature to "**expand the functions**" of a stethoscope. The specification further discloses numerous expanded functions that can be added to a stethoscope beyond the basic one of listening to a patient. Once again, the "marketplace" test in KSR suggests the non-obviousness of the present invention. Not only, as stated above, is there no stethoscope that can be expanded via software, there is currently no stethoscope in the marketplace that has any method whatsoever of expanding the functions of a stethoscope beyond listening to patients.

One must inevitably conclude that 16 years after Bredesen, 9 years after the priority date of the present invention, those with ordinary skill, inventing new stethoscopes, have yet to produce the claimed invention or even limited features of the claimed invention despite the fact that all major companies in this field released new products during this time period. Were this obvious in light of the prior art, or obvious if one applied knowledge and common sense and even hindsight, we would expect marketplace activity to have produced the present invention.

The above arguments are further consistent with the tests applied under Graham. It is clear that if one considers (a) prior art as cited by Examiner (b) differences between prior art and the claimed invention as discussed above and in previous communications with Examiner,

(c) the level of ordinary skill (even when considered with some hindsight) and (d) evaluating evidence of secondary consideration (as discussed above in light of KSR); one must conclude that the claimed invention passes the Graham test.

Therefore, under present patent examination guidelines under Graham and KSR, Claim 19 and its dependent claims are clearly allowable.

RESPONSE TO EXAMINER REMARKS CLAIMS 20-36

Response to Examiner's Remarks, Office Action Dated March 7, 2007 regarding dependent Claims 22 – 31:
Claim 19 has been amended after lengthy discussions with Examiner. Claims 22-31 are dependent claims of Claim 19, and therefore addressed by the discussion of the amended Claim 19. Applicant has also previously responded to Examiner's comments regarding claims 22-31.

Responses to Examiner's Remarks Office Action Dated March 7, 2007 regarding claims 32-33, 35, 36:

Claim 32-33: Examiner agrees that Bredesen does not disclose more than one physiological measurement means, as claimed in the present invention and has not cited any prior art for placement of blood oxygen measurement in a stethoscope housing, presumably agreeing that the placement of blood oxygen measurement within a stethoscope housing is allowable. Examiner cites Iliff's glucometer as an example of multiple physiological measurements. However, Iliff does not disclose the housing of such multiple measurement means within a wearable stethoscope and does not provide motivation to do so. The prior art makes no suggestion or motivation to combine Bredesen's stethoscope with Iliff's glucometer. Examiner has not stated a reason why a person of ordinary skill would place Iliff's glucometer within a stethoscope. Applicant thus submits that the combination of Iliff and Bredesen as presented by Examiner is a hindsight reconstruction based on Applicant's invention and it would be incumbent on examiner to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

Claim 35: Applicant has amended Claim 35 to remove references to the barcode scanner, thereby addressing Examiner's concerns regarding prior art disclosed by Plesko. There is no prior art suggestion or motivation for the combination of stethoscope and video input means and therefore the amended claim would be allowable.

Claim 36: Examiner agrees that Bredesen does not disclose a second input for detecting voice sound as claimed in the present invention. Examiner cites Grasfield (US 5,825,895 Fig 1,2,8 and Col. 6 lines 49-56) as having a microphone for detecting voice sound. Examiner's reference to Grasfield states that:

> The second acoustic conduit 52 continues through electronic housing 16, spring and switch housing 26 and continues through the first binaural 32. A microphone 54 is

located near the end 34 of the second binaural 30. **Microphone 54 picks up the sounds transmitted through the chestpiece 12 and acoustic conduit 52** and converts the acoustic signal into electronic signals that are processed by the electronics circuitry located in the electronics housing 16.

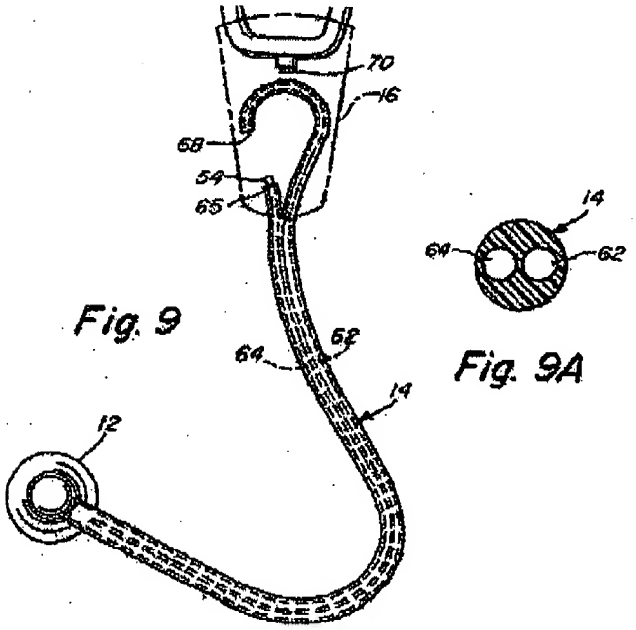

Fig. 9

Fig. 9A

In the figure shown (Grasfield Fig 9), and according the quoted description, Grasfield has only **one** microphone, and that microphone is placed to **receive sound from the chestpiece** i.e. from the human body when using the stethoscope to listen to patients. The other conduit 68 does not have any microphone at all and is also **intended for listening to the patient**, but without any amplification presumably. Grasfield at no time suggests anything related to a second microphone for the purpose of detecting voice, and does not suggest that a stethoscope provide a feature to detect voice sounds. On the contrary, Grasfield's microphone is placed such that it detects sounds through the tubing connected to the chestpiece i.e. listening to patients hearts and lungs as in a stethoscope.

Applicant thus submits that Grasfield does not disclose, suggest or motivate the claimed invention. There are not two audio input means in Grasfield, and there is no means for detecting both voice sounds along with body sounds. The prior art therefore neither suggests nor motivates claim 36. Under the KSR guidance on considering common sense, there is no obvious reason to provide a stethoscope with voice detection means. The combination as claimed is entirely non-obvious.

SUPPORT FOR AMENDED CLAIM 19 IN THE SPECIFICATION

Examiner has requested that Applicant provide support for amended Claim 19 in the Specification.

Claim 19: An electronic stethoscope with expanded program execution and communications capability, comprising:

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements comprising

Central processing unit,

Nonvolatile digital memory means selected from a group consisting of Flash memory, EEPROM, and magnetic media,

One or more software programs, executable by said central processing unit, which expand the functions executed by said stethoscope,

Said functions comprising medical measurement, information processing and communications functions,

Digital communications means,

Wherein said software programs are transferred via said digital communications means, stored in said nonvolatile digital memory means, and executed by said central processing unit.

The following provides references to the Specification, in support of Claim 19. Note that page and line numbering quoted here may differ from Examiner's copy of the present invention. (Bold indended text is the claim language. This is followed by quotes from the Specification in support of the claim.)

An electronic stethoscope with expanded program execution and communications capability, comprising

Specification: The preferred embodiment is in the form of a stethoscope-like device with expanded, general-purpose medical measurement, information and communications functions, beyond the basic auscultation functions. (Field and Background of the Invention, Page 1, lines 10-13).

A portable housing in the physical form of a stethoscope that is wearable around the neck or shoulders of an operator, to house further elements comprising

Specification: The form factor of the stethoscope allows it to be worn comfortably around the neck or shoulders (Field and Background of the Invention, Page 2, lines 15-16).

Central processing unit

Specification: Central Processor/ Digital Signal Processor 120 (Electronic Processing sub-system 102 Line 23 and Fig 1)

Nonvolatile digital memory means selected from a group consisting of Flash memory, EEPROM, and magnetic media

Specification: Nonvolatile technologies include but are not limited to Flash, EEPROM, or magnetic media. (Electronic Processing sub-system 102, section (b) Digital Memory, Page 7 lines 11-12)

One or more software programs, executable by said central processing unit, which expand the functions executed by said stethoscope

Specification: The Electronic Processing sub-system 102, provides hardware, firmware, software and storage functionality, and is operationally connected to the Sensor subsystem 101, User Input sub-system 103, Communications sub-system 104, or Output/Display sub-system 105. The Electronic Processing sub-system consists of one or more of the following elements:
(a) **Central Processor**/ Digital Signal Processor 120,
(Electronics Processing sub-system 102, Page 6)

Specification: Digital Memory 121, which stores programs (**software**) (Page 6, line 28)

Specification: However, the transition from a mechanical to an electronic stethoscope introduces the potential to **expand the functionality of the stethoscope**, using it as a more general-purpose electronic platform for other functions that are useful to the medical worker. (Page 2, lines 11-15)

Said functions comprising medical measurement, information processing and communications functions,

Specification: The preferred embodiment is in the form of a stethoscope-like device with expanded, general-purpose medical measurement, information and communications functions, beyond the basic auscultation functions. (Field and background of the Invention Page 1, lines 10-13)

Digital communications means

Specification: (See Detailed Description of the Preferred Embodiment, entire section on Communications sub-system 104 page 8.)

Wherein said software programs are transferred via said digital communications means, stored in said nonvolatile digital memory means, and executed by said central processing unit.

Support: The references to the Specification, provided below, taken together, disclose the above section of the claim as follows: The Communications sub-system (**communications means**) operates on protocols that facilitate **transfer** such as File Transfer Protocol (FTP). The Communications sub-system can **transfer** all data types that can be stored in the Digital Memory. The specification discloses that **software** can be stored in the Digital Memory. Hence, **software** can be **transferred** via the Communications sub-system (**communications means**). Once in Digital memory, the specification discloses an Electronic Processing sub-system which contains a **central processing unit** which can access the digital memory i.e. **execute** the software in digital memory. The references to the Specification below disclose all of these elements, thereby supporting the entire claim and all its elements:

Specification: Software in the Electronics Processor or the Communications sub-system itself controls the operations of the communications channel. This includes software protocols including, but not restricted to, TCP/IP, PPP, FTP, or other Internet protocols. (Communications sub-system Page 8, lines 35-38)

Specification: The Communications sub-system is intended to provide information exchange beyond auscultation information, for broader medical data purposes. The data types include, but are not limited to, any of the data stored in the Digital Memory, and described under the Digital Memory section. (Communications sub-system Page 9 lines 5-8)

Specification: Digital Memory 121, which stores programs (software), (Electronic Processing sub-system 102, Page 6 line 28).

Specification: The Electronic Processing sub-system 102, provides hardware, firmware, software and storage functionality, and is operationally connected to the Sensor subsystem 101, User Input sub-system 103, Communications sub-system 104, or Output/Display sub-system 105. The Electronic Processing sub-system consists of one or more of the following elements:
(a) **Central Processor**/ Digital Signal Processor 120,
(Electronics Processing sub-system 102, Page 6)

Respectfully submitted,

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